



Board of Health

Edward Cosgrove, PhD
Vice Chair, Board of Health

Stephen Epstein, MD, MPP
Chair, Board of Health

Jane Fogg, MD, MPH
Member, Board of Health

ARTICLE 24 REGULATION TO ENSURE THE SANITARY AND SAFE OPERATIONS OF COMMERCIAL AND RECREATIONAL MARIJUANA ESTABLISHMENTS, AND TO MINIMIZE COMMUNITY IMPACTS AND COLLATERAL CONSEQUENCES OF WIDESPREAD RECREATIONAL MARIJUANA USE AND BOTH COMMERCIAL AND PERSONAL MARIJUANA CULTIVATION

SECTION 24.1 AUTHORITY

This regulation is promulgated under the authority granted to the Needham Board of Health under Massachusetts General Laws Chapter 111, Section 31 which states that "boards of health may make reasonable health regulations," and to Section 122 of the same chapter of the Massachusetts General Laws which states, in part, that "the board of health shall examine into all nuisances, sources of filth and causes of sickness within its town, or on board of vessels within the harbor of such town, which may, in its opinion, be injurious to the public health, shall destroy, remove or prevent the same as the case may require, and shall make regulations for the public health and safety relative thereto..."

Board of Health Regulations are an exercise of the police power under which the various levels of government are responsible for protection of the public health, safety, and welfare.

Additionally, this regulation is promulgated pursuant to **DETAILS OF STATE BALLOT LANGUAGE AND/OR CANNABIS CONTROL COMMISSION REGULATIONS. ~~Chapter 369~~** of the Acts of 2012 An Act for the Humanitarian Medical Use of Marijuana ("The Act") and **Massachusetts Department of Public Health Regulations 105 CMR 725.000.**

SECTION 24.2 PURPOSE & RATIONALE

24.2.1 – PURPOSE FOR REGULATION

The primary purpose of this regulation is to provide for local oversight and inspection of Commercial and Retail Marijuana Establishments (CRMEs) and also to provide for the local oversight and inspection marijuana cultivation sites within the Town of Needham, whether commercial or personal in nature.

Under this regulation, Needham's Board of Health and its agents shall provide oversight and inspections to ensure the safe and sanitary operation of any such CRME or commercial or personal cultivation site within the Town of Needham. The oversight and corresponding inspections shall be consistent with public health and safety standards, and will incorporate **DETAILS OF STATE BALLOT LANGUAGE AND/OR CANNABIS CONTROL COMMISSION REGULATIONS.**

The regulation is intended to ensure that only people age 21 years or older will acquire marijuana or marijuana-infused products pursuant to **the Act**, and that marijuana will not be diverted to individuals under the age of 21. Since the existence of a CMRE or any marijuana cultivation site present a risk of improper diversion and other collateral consequences within the community, it is necessary to regulate this activity at the local level.

24.2.2 – RATIONALE FOR REGULATION, INCLUDING PUBLIC HEALTH REASONS

WORK IN PROGRESS

Charged with the protection of the public health, boards of health fulfill their duty by developing, implementing, and enforcing health policies. "The focus of public health is to protect the health of every member of a community." American Lithuanian Naturalization Club, Athol, Mass., Inc. & others v. Board of Health of Athol & another, 446 Mass. 310 (2006). One step in this process is the adoption of local health regulations pursuant to Massachusetts law. Boards of health have statutory powers to develop regulations in many areas of environmental health. G.L. c.111, §31 gives boards general regulatory power to adopt reasonable health regulations. §§31A and 31B address the removal, transportation and disposal of refuse. Section 122 addresses nuisances, §127 addresses house drainage and sewer connections. §127A addresses the sanitary code and §143 addresses (noisome/offensive trades).

Board of health regulations "stand on the same footing as would a statute, ordinance or by-law." Druzik v. Board of Health of Haverhill, 324 Mass. 129, 138 (1949). Moreover, "[a]ll rational presumptions are made in favor of the validity of [the regulations]." Id. Courts will only strike a Board of Health regulation when the challenger proves, on the record, "the absence of any conceivable ground upon which [the rule] may be upheld." Arthur D. Little, Inc. v. Com'r of Health, 395 Mass. 535 (1985) (quotation and citations omitted). If the public health issue is "fairly debatable," the court cannot

substitute its own judgment for that of the Board of Health. Id. (citations omitted). Said rule preserves the separation between the powers of the legislature and its administrative agencies and those of the judiciary. Id. (citations omitted). In addition, said rule acknowledges that Boards of Health are the experts in the area of public health policy. Id. (citations omitted).

The Supreme Judicial Court has repeatedly upheld the broad regulatory authority of boards of health. Most recently, the Court upheld a regulation that prohibited all smoking in private clubs. American Lithuanian Naturalization Club, Athol, Mass., Inc. & others v. Board of Health of Athol & another, 446 Mass. 310 (2006). Stating nothing in G.L. c.111, §31, or our prior case law warrants a conclusion that members of a community may be protected by health regulations only when they are in a location to which the public has access. Even if smoking members choose to disregard the overwhelming evidence of the serious health consequences of smoking, the board rationally could be concerned about the exposure of non-smokers to a “known human carcinogen” Id.

Additionally, boards of health have broad authority to enforce their regulations. See G.L. c.111, §27 (authorizing Boards of Health to “employ the necessary officers, agents and assistants to execute the health laws and its regulations”). Boards may issue enforcement orders. In the event the order is ignored, Boards of Health may seek and obtain injunctive orders in superior court restraining violations of their regulations. G.L. c.111, §187, §189. Boards of health may also suspend, revoke or refuse to issue a permit after a hearing, notice and opportunity to be heard. Butler v. Town of E. Bridgewater, 330 Mass. 33, 38, 110 (1953). In addition, boards may levy specified fines and collect them through criminal proceedings in district court. E.g. G.L. c.111, §31; G.L. c. 111, §122; G.L. c. 111, §31C. Alternatively, boards may, if authorized by the municipality, issue tickets and thereby collect fines through the less arduous non-criminal method of disposition. G.L. c.40, §21D. Additionally, boards of health may, if authorized by the municipality, suspend any license it has issued to any person who has neglected and/or refused to pay a fine issued under the non-criminal method of disposition. G.L. c.40, §57.

A person’s business is a property right and is therefore entitled to protection against regulations that violate constitutional guaranties. Unless the regulation is justified as a valid exercise of the police power, the regulation would be declared unconstitutional because enforcement would deprive a person of his property without due process of law. Duplex Co. v. Deering, 254 U.S. 443, 465 (1921), *quoted in* S.S. Kresge Co., 267 Mass. at 151. Persons regulated pursuant to a valid regulation, however, cannot complain that their business has been injured by the exercise of the police power for the benefit of the public health. “The right to engage in business must yield to the paramount right of government to protect the public health by any rational means.” Druzik, 324 Mass. at 139; Lawrence v. Board of Registration in Medicine, 239 Mass. 424, 428 (1921).

Regulations may be prospective in nature. That is, boards of health may require precautions to avoid potential dangers as well as to restrict conditions actually harmful. City of Waltham v. Mignosa, 327 Mass. 250, 251-52 (1951); Commonwealth v. E.E. Wilson Co., 240 Mass. 406, 410, (1922); Town of Holden v. Holden Suburban Supply Co., Inc., 343 Mass. 187, 191 (1961).

Regulations adopted pursuant to the board's rule making authority, such as regulations adopted under §31 and §43, do not require a hearing (unless they are relative to Title V, see, Chapter 4) or findings of fact. Arthur D. Little v. Commissioner of Health and Hosp. of Cambridge, 395 Mass. 535, 543 (1985). "It is well established that agency is not obligated to provide a statement of reasons which support its adoption of a regulation." Borden, Inc. v. Commissioner of Pub. Health, 388 Mass. 707, 723 n.9, *cert. denied stub nom. quoted in* Arthur D. Little, 395 Mass. At 543. Formaldehyde Inst., Inc., v. Frechette, 464 U.S. 936 (1983).

§31 of G.L. c.111, is an unusually broad grant of authority which empowers boards of health to adopt "reasonable health regulations." The power of boards of health to adopt regulations under §31 is extensive. Enactment of §31 "provided a comprehensive, separate, additional source of authority for health regulations." Board of Health of Woburn v. Sousa, 338 Mass. 547, 550 (1959). "[Section] 31 was passed as legislation of broad and general scope, after [the predecessor statutes] had been on the statute books for many years. The legislative history shows no purpose to limit its scope." Id. at 551-52.

In Brielman v. Commissioner of Pub. Health of Pittsfield, 301 Mass. 407 (1938), the city board of health had adopted a regulation prohibiting the sale of unpasteurized milk unless it had been certified according to provisions of state law. The regulation prevented the sale of three of the eight classes of milk established by the state of milk regulation board. The regulation was challenged and the court stated that boards of health "may make regulations that are more stringent than the general law." Id. at 410. A strict insistence upon a high standard of purity and safety in milk, in fact higher than that required by the state, was determined to be well within the police power.

The case law is clear that municipal boards and officials do not need statutory authority to adopt licensing and permit fees. Any statutory authorization to a municipality or to a board to regulate includes authorization to require licenses and licensing fees "to cover reasonable expenses incident to the enforcement of the rules". Commonwealth v. Plaisted, 148 Mass. 375, 382 (1889), *quoted in* Southview Co-operative Hous. Corp. v. Rent Control Bd. Of Cambridge, 396 Mass. 395, 400 (1985).

Further, if the authority to regulate includes the authority to require licenses and licensing fees, the authority to regulate also includes the authority to exact fees to defray the cost of conducting hearings and performing other services. Southview Co-operative Hous Corp., at 400. As the court observed in Boston v. Schaffer, 26 Mass (9 Pick) 415, 419 (1830), "[t]owns are put to expense in preserving order and it is proper that they should be indemnified for inconveniences or injuries occasioned by employments of this nature". G.L. c.40, §22F

Even though boards have inherent authority to adopt licensing and user fees, the legislature has specifically provided statutory authorization for the imposition of such fees and charges. G.L. c. 40, §22F authorizes municipal boards or officials empowered to issue a license, permit or perform a service or work to fix reasonable fees after the municipality has accepted the provisions of §22F by a vote of town meeting or the city council. G.L. c. 44, § 53G provides that certain municipal board regulations, including the board of health's regulations adopted under G.L. c.31, §111, can provide for the imposition of reasonable fees for the employment of outside consultants.

DRAFT

SECTION 24.3 DEFINITIONS

Unless otherwise indicated, terms used throughout this regulation shall be defined as they are in [105 CMR 725.004](#).

Board of Health: Town of Needham Board of Health and its designated agents.

Board of Health Agent: The Director of Public Health and any town employee designated by the Director, which may include Public Health Department staff, law enforcement officers, fire officials, and code enforcement officials.

Business Agent: A Dispensary Agent, as also defined in [105 CMR 725.004](#), who has been designated by the RMD Permit Holder to be a manager in charge of the RMD facility and its operations.

Card Holder: A registered qualifying patient, a personal caregiver, or a dispensary agent of a RMD who has been issued and possess a valid registration card.

Commercial and Recreational Marijuana Establishment (CRME): A Commercial and Recreational Marijuana Establishment is an entity ~~registered under 105 CMR 725.100~~, that acquires, cultivates, possesses, processes (including development of related products such as edible MIPs, tinctures, aerosols, oils, or ointments), transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, or educational materials to customers age 21 or older. The term CRME may also refer, in context, to the site(s) of dispensing, cultivation, and preparation of marijuana by a CRME entity.

CRME Agent: A CRME Agent is a board member, director, employee, executive, manager, or volunteer of a CRME, who is at least 21 years of age. Employee includes a consultant or contractor who provides on-site services to a CRME related to the cultivation, harvesting, preparation, packaging, storage, testing, or dispensing of marijuana.

CRME Permit: A Commercial and Recreational Marijuana Establishment Permit, to be renewed annually, which may be issued by the Board of Health to an applicant [pursuant to 105 CMR 725.000](#), which permits a CRME to operate within the Town of Needham.

Director: The Director of Public Health.

Home Permit: Issued by the Board of Health, to be renewed annually, which allows the permit holder to cultivate up to six marijuana plants at a specific location within the town. That location is subject to a health and safety inspection and approval by the Director and his designated agents.

Non-Residential Roll-Your-Own (RYO) Machine: A mechanical device made available for use (including to an individual who produces rolled marijuana products solely for the

individual's own personal consumption or use) that is capable of making rolled marijuana products. RYO machines located in private homes used for solely personal consumption are not Non-Residential RYO machines.

Period of Performance: The time period for which violations of a CRME or Home Permit are counted. For example, a violation that occurs in July 2017 will no longer weigh on the CRME or Home Permit holder's record with the Board of Health after the passage of 60 months from the date of the discipline imposed for that violation. If the Board of Health hearing on the violation occurred on July 31, 2017, then the violation will be outside the period of performance and no longer counted on August 1, 2022.

Self-Service Display: Any display from which customers may select marijuana or a marijuana-infused product without assistance from a Commercial and Recreational Marijuana Establishment.

Town: The Town of Needham, Massachusetts.

Vending Machine: Any automated or mechanical self-service device, which upon insertion of money, tokens or any other form of payment, dispenses or makes marijuana products.

Violation: A failure to comply with an operational requirement outlined in this regulation. For this regulation, a MINOR violation is a failure to comply with specific regulatory requirements, which, while important, do not jeopardize the primary purposes of this regulation. A MAJOR violation is one that has the potential to jeopardize the primary purposes of this regulation, meaning that non-compliance in this area may divert marijuana to individuals under the age of 21 and/or which may produce significant collateral consequences to community health and public safety.

SECTION 24.4 PERMIT TO OPERATE A REGISTERED MARIJUANA DISPENSARY

24.4.1 – Permits for a Registered Marijuana Dispensaries

- A. No person or organization shall sell or otherwise distribute marijuana or marijuana-infused products within the Town of Needham without first obtaining a RMD Permit. A RMD Permit may only be issued to a nonprofit corporation which:
- (i) has a current Certificate of Registration issued by the Massachusetts Department of Public Health (DPH) pursuant to 105 CMR 725.000; and
 - (ii) has a permanent, non-mobile location in Needham approved by the DPH for use as an RMD; and
 - (iii) is in compliance with all applicable zoning requirements.
- And which provides satisfactory documentation of compliance with those requirements to the Board of Health.
- B. The applicant shall also submit to the Board of Health a copy of the operating policies and procedures for the RMD which was submitted to DPH pursuant to 105 CMR 725.000 and any other relevant DPH directives, memorandums or notifications.
- C. The applicant shall sign a statement declaring that the applicant understands that, under this local regulation:
- (i) all Dispensary Agents are responsible for complying with all local and state regulations pertaining to the operation of the RMD. Specifically, a violation of any provision of 105 CMR 725.000 or other applicable state regulations constitutes a violation of this regulation, which may be enforced by the Board of Health; and
 - (ii) the applicant is responsible for providing instruction and training for dispensary agents in all applicable local and state regulations; and
 - (iii) the fact that a Dispensary Agent, vendor, or other person associated with the RMD is unaware of a regulation or lacks understanding of its content, shall not be a defense to any violation; and
 - (iv) the Board of Health and its designated agents may conduct periodic, unannounced inspections of the RMD premises.
- D. The fee for a RMD Permit shall be at the level determined in the Needham Board of Health's Fee Schedule. All RMD Permits expire on June 30 annually, regardless of the year or day and month on which they were issued.
- E. The initial plan review for marijuana-infused product (MIP) production facilities (see section 20.5.1) shall result in a fee at the level determined in the Needham Board of Health's Fee Schedule. The initial plan review for the safe and sanitary storage of marijuana-infused products in a RMD (see section 20.5.2) shall result in a fee at the level

determined in the Needham Board of Health's Fee Schedule. The initial plan review for trash collection and the safe and sanitary disposal of waste (see section 20.5.3) shall result in a fee at the level determined in the Needham Board of Health's Fee Schedule. The plan reviews for emergencies and continuity of operations (see section 20.5.4) and for safety and security (see section 20.5.5) shall result in a fee at the level determined in the Needham Board of Health's Fee Schedule.

- F. RMD Permits in good standing may be renewed annually by the Board of Health, at the Board's discretion, based on a completed and satisfactory application, in a form required by the Board, filed by the RMD and payment by the RMD of the annual fee according to the fee schedule.
 - (i) Any material changes from the most recent approved operating policies and procedures, or from the plans described in Section E above shall be disclosed in the renewal application, and RMD shall pay the applicable fees for any reviews which the Board deems necessary as a condition of renewal.
 - (ii) If a permit has been modified by the Board, the RMD shall demonstrate compliance with any requirements of that modification, to the satisfaction of the Board, as a condition of renewal and shall pay the applicable fees for any reviews which the Board deems necessary as a condition of renewal.
 - (iii) If a permit has been suspended by the Board, prior to reinstatement of the permit, the RMD shall provide evidence satisfactory to the Board that it will comply with all requirements of the Board and these regulations, and shall pay the applicable fees for any reviews which the Board deems necessary as a condition of renewal
 - (iv) If a permit has been revoked by the Board, the RMD permit may be reissued based on a new application, all necessary fees, and a public hearing.
- G. A separate RMD Permit is required for each RMD retail establishment selling marijuana or marijuana-infused products within the Town. A violation of this provision constitutes a MINOR violation of these regulations.
- H. Each RMD Permit shall be displayed at the RMD retail establishment in a conspicuous place. A violation of this provision constitutes a MINOR violation of these regulations.
- I. A RMD Permit is non-transferable. A violation of this provision constitutes a MINOR violation of these regulations.
- J. A RMD Permit will not be renewed if the RMD Permit Holder has failed to pay any outstanding fines or fees or failed to satisfy any other penalties or conditions lawfully imposed by the Town.

- K. A RMD may not open for business before 8:00 A.M. and shall close no later than 8:00 P.M., on each day the RMD is open. Deliveries from, or on behalf of, the RMD that are made to patients must adhere to the same hours. The hours and days of RMD operation must be posted conspicuously on the front entrance door. A violation of this provision constitutes a MINOR violation of these regulations.
- L. Acceptance of a RMD Permit constitutes an agreement by the RMD that it will adhere to the practices, policies, and procedures described or submitted with its application, as well as the relevant laws, state and local regulations, and conditions imposed by the Board of Health as part of the permit process.

20.4.2 – Inspections and Compliance of Registered Marijuana Dispensaries

- A. Dispensary Agents must present their Registration Card on request by any Board of Health agent. A violation of this provision constitutes a MINOR violation of these regulations.
- B. Issuance and maintaining a RMD Permit shall be conditioned on the RMD Permit Holder's ongoing consent to periodic, unannounced inspections of the RMD premises by the Board of Health and its designated agents. The applicant also consents to abide by the provisions relating to inspections found in 105 CMR 725.300 and related sections including, but not limited to, "deficiency statements" and "plans of correction." A violation of this provision constitutes a MINOR violation of these regulations.
- C. There must be a designated Business Agent on the premises at all times that the RMD is open for business. A violation of this provision constitutes a MINOR violation of these regulations.
- D. The Board of Health and its designated agents, as well as the Needham Police Department, shall be provided with an updated phone list through which a Business Agent may be reached on a 24 hour basis. A violation of this provision constitutes a MINOR violation of these regulations.
- E. Issuance and maintaining a RMD Permit shall be conditioned on the RMD Permit Holder's ongoing consent to provide the Board of Health with copies of the Registration Cards for all Dispensary Agents working at the RMD, and the names of all Business Agents of the RMD, and to submit any changes in staffing and registration information within five (5) business days. The notification and information about changes in staffing and registration shall be submitted in either paper copy via courier or certified mail or else electronically in a verified/e-signed PDF format. A violation of this provision constitutes a MINOR violation of these regulations.
- F. The RMD Permit Holder shall Criminal Offender Record Information (CORI) inquiry and a Sex Offender Registry Information (SORI) inquiry on all applicants for the positions of

Dispensary Agent and for Business Agents. Such checks shall be conducted in all states in which the applicant has worked or resided within the last ten (10) years. The results of those inquiries shall be reported to the Needham Public Health Department. A violation of this provision constitutes a MINOR violation of these regulations.

- G. Issuance and maintaining a RMD Permit shall be conditioned on the RMD Permit Holder's ongoing consent to provide the Board of Health with updated copies of all RMD documents including copies of staffing plans, training protocols, audit results, security assessments (subject to appropriate redaction), and all other documents. Updated submissions shall be sent to the Board of Health monthly electronically in a verified/e-signed PDF format. A violation of this provision constitutes a MINOR violation of these regulations.
- H. No RMD Permit Holder shall permit any disorder, disturbance, or illegality of any kind to take place in or on the licensed premises. The term "illegality" includes, but is not limited to, any violation of 105 CMR 725.000 and related directives, memoranda or notifications; and any violation of these regulations promulgated by the Board of Health. The Permit Holder shall be responsible for any disorder, disturbance or illegality of any kind whether present or not. A violation of this provision shall be considered may be considered either a MINOR or a MAJOR violation depending upon the severity of the illegality identified.
- I. Failure or refusal of an RMD or Home Permit holder to cooperate with the Board of Health or its agent shall be considered a MAJOR violation of these regulations.

20.4.3 – Records Retention of Registered Marijuana Dispensaries

- A. A RMD Permit Holder shall notify the Needham Public Health Department and the Board of Health verbally and in writing within 24 hours of a visit to the premises or request for information by any representative of DPH acting in an official capacity. The RMD Permit Holder shall provide the Board with any reports, correspondence, emails or other information from DPH on demand or, in any case, within five (5) business days after receipt by the RMD. A violation of this provision constitutes a MINOR violation of these regulations.
- B. Video surveillance shall conform to the requirements of 105 CMR 725.110(D) and any other related regulations, directives, memorandums or notifications from DPH. In addition, as conditions of issuing or maintaining its RMD Permit, the Board of Health may require other, reasonable surveillance operations and security (e.g., an off-site backup system). Furthermore, the RMD must allow for immediate viewing of video surveillance by the Board of Health or its designated agents, upon request. A copy of a requested recording shall be provided as soon as practicable to these officials. All video recordings shall be retained for a minimum of 90 days. Furthermore, as soon as the

RMD is aware of any recording that might relate to a criminal, civil or administrative investigation or legal proceeding of any kind, the RMD shall not alter or destroy the recording without the written permission of both the Director and the Chief of Police for the Town of Needham. A violation of this provision constitutes a MAJOR violation of these regulations.

- C. Issuance and maintaining a RMD Permit is conditioned on maintaining all records outlined in 105 CMR 725.105(I) and other DPH regulations, directives, memorandum and notifications, along with any other documents reasonably required by the Board of Health in writing. Following closure of an RMD, all records must be kept for at least two (2) years at the expense of the RMD and in a form and location acceptable to the Board of Health. Moreover, as a condition of issuing and maintaining a RMD Permit, the Board of Health may reasonably require that the new owner of a RMD retain records generated by the previous RMD at the expense of the new RMD. A violation of this provision constitutes a MINOR violation of these regulations.

20.4.4 – Other Restrictions for Registered Marijuana Dispensaries

- A. For RMDs that cultivate marijuana, the cultivation and processing facility shall not adversely affect the health or safety of the nearby residents or businesses by creating dust, glare, heat, noise, nuisance odors, noxious gases, materials, processes, products or wastes. Growing areas shall be within a self-contained, locked structure, with a 1-hour firewall assembly made of green board or other construction specifically approved by the Town's building inspector, well ventilated with odor control, and shall not create humidity or mold issues within the establishment. A violation of this provision constitutes a MAJOR violation of these regulations.
- B. No RMD is permitted to sell or distribute alcoholic beverages or tobacco products and may not hold either a tobacco sales permit or a liquor license. A violation of this provision constitutes a MAJOR violation of these regulations.
- C. No RMD is permitted to hold a Common Victualler license for on-premises food consumption. A violation of this provision constitutes a MAJOR violation of these regulations.
- D. No RMD is permitted to be a Massachusetts lottery dealer or to engage in any gaming activities. A violation of this provision constitutes a MAJOR violation of these regulations.

SECTION 24.5 PLAN REVIEWS OF COMMERCIAL AND RECREATIONAL MARIJUANA ESTABLISHMENTS

24.5.1 – Off-Site Cultivation/MIP Preparation Plan Review

An applicant who wishes to sell edible marijuana-infused products (MIPs) at a CRME must, prior to beginning operations, undergo a plan review of any MIP processing and preparation facilities, regardless of their location, for any MIP that will, at some point, be delivered, distributed, produced, sold, or stored within the Town. The Board of Health and its designated agents will conduct the plan review, which may include a facilities inspection, to ensure sanitary handling and processing conditions and practices.

24.5.2 – Plan Review for MIP Storage and Handling at CRME Location

An applicant who wishes to sell edible marijuana-infused products (MIPs) at a CRME must, prior to beginning operations, undergo a plan review of all MIP storage, handling, and sale locations within the CRME. The Board of Health and its designated agents will conduct the plan review, which may include a facilities inspection, to ensure sanitary handling and storage conditions and practices in line with the requirements outlined in the [105 CMR 590](#), the State Sanitary Code.

The requirements of 105 CMR 590.000 include specific actions to prevent the growth of bacteria. *Clostridium botulinum* is a bacterium whose spores are present on plant material and in soil. Spores are present in many plant material extractions and can survive cooking/pasteurization temperatures. These spores can spontaneously germinate (grow into bacteria) given the right conditions/substrate. The bacteria can produce a powerful toxin that can cause severe illness or death. Specific actions required of a CRME selling MIP are:

- A. Except during preparation, cooking, or cooling, time/temperature control for safety (TCS) items shall be maintained at 5°C (41°F) or less to prevent the growth of bacteria. This shall apply, unless specifically permitted by the Board of Health or its agents, to all:
 - (i) marijuana extractions and concentrates intended for non-smoking oral consumption (i.e. eating, drinking);
 - (ii) infusions made from those extractions, such as infused oils, butters, honey, etc; and
 - (iii) foods that have such infusions/extractions as an ingredient.
- B. If a marijuana extraction, concentrate, or infusion has been continuously refrigerated and is then added as an ingredient into baked goods that have a low water activity, such as most cookies and brownies, these baked products may be considered shelf-stable if explicitly reviewed and permitted by the Board of Health or its agents.
- C. If the extracted marijuana concentrate is immediately infused into a 190/200 proof alcohol with no additional ingredients (including flavorings or other additives) and the tincture is homogenous, then the growth of *C. botulinum* spores may have been prevented. Homogenous 190/200 proof alcohol tinctures may be safe to store outside

of refrigerated temperatures if explicitly reviewed and permitted by the Board of Health or its agents.

- D. Approvals for any variance from the safe and sanitary storage requirements outlined above will be based upon:
- (i) a review of written procedures that are followed to make the product;
 - (ii) the use of control measures described above; and
 - (iii) any other scientific evidence submitted by the manufacturer from a certified laboratory or process authority that demonstrates the safety of the product in question. For example:
 - a) pH and/or water activity testing must be conducted by an accredited laboratory;
 - b) three samples from separate batches must be tested; and
 - c) all samples must meet the criteria for a non-potentially hazardous food as described in Tables A and B of the 2013 *FDA Food Code*.
- E. At any time, the Board of Health or its agents may require a Hazard Analysis and Critical Control Points (HACCP) plan before approving the distribution of MIPs.
- F. Photos or images of food are not allowed on MIP product labels.
- G. All MIP must be contained in an opaque package.
- H. If the MIP is identified on the label using a common food name (i.e. Brownie, Honey, Chocolate, Chocolate Chip Cookie, or Green Tea), the phrase “MARIJUANA—NOT FOR PEOPLE UNDER 21” must be written before the common food name. This phrase must be as easy to read as the common food name (i.e. same font size).
- I. Only generic food names may be used to describe the MIP. As an example, using “Snickerdoodle” to describe a cinnamon cookie is prohibited.
- J. All MIP must state the following:
- (i) A batch number, sequential serial number, and bar code when used, to identify the batch associated with manufacturing and processing;
 - (ii) A statement that the product has been tested for contaminants, that there were no adverse findings, and the date of testing in accordance with 105 CMR 725.105(C)(2);
 - (iii) The manufacture date as well as a “Best by” or “Use by” or expiration date;
 - (iv) Net weight of Marijuana and the THC level in the MIP, and the net weight of Marijuana and the THC level contained per dose/serving (if the MIP is not a single serving/dose);
 - (v) A list of ingredients as well as the cannabinoid profile of the marijuana contained within the MIP;
 - (vi) A warning if nuts or other known allergens are contained in the product;

- (vii) Directions for use of the product if relevant;
- (viii) The statement "For ADULT Use Only"; and
- (ix) The statement, including capitalization: "This product has not been analyzed or approved by the FDA. There is limited information on the side effects of using this product, and there may be associated health risks. Do not drive or operate machinery when under the influence of this product. KEEP THIS PRODUCT AWAY FROM CHILDREN."

Each violation of any of the provisions of 24.5.2 (A) through (J) shall constitute a MINOR violation of these regulations.

24.5.3 – Plan Review for Safe and Secure Disposal of Waste, Refuse, or Damaged Product

An applicant for a CRME Permit shall develop a plan for the safe and secure storage and disposal of any waste, refuse, or damaged marijuana, MIPs, and related products. Such a plan will be based on the requirements outlined in 105 CMR 725.105(J) and will be subject to review and approval by the Board of Health and its designated agents prior to the RMD beginning operations.

24.5.4 – Plan Review for Emergencies and Continuity of Operations

In accordance with emergency planning requirements specified in 105 CMR 725.105(A)(9) and similar to the responsibilities outlined in the Risk Management and Continuous Quality Improvement section of the *Guidelines for the Accreditation of Opioid Treatment Programs* which are authorized in 42 CFR 8.12(c), an applicant for a RMD Permit shall develop an emergency management program to ensure the safety of its staff and customers and a mechanism by which to ensure the continuity of its operations (COOP) in response to inclement weather, man-made emergencies, supply chain disruptions, or discipline (including permit suspension) which result in the RMD being unable to provide medical marijuana and MIPs to patients with a documented medical need. Such a program shall include:

- A. A detailed emergency operations plan (EOP) and a process by which staff will be trained on that plan and their knowledge of it tested via drills and exercises. The emergency operations plan will:
 - (i) Include a set of contact procedures for staff, customers, and community partners in the event of an emergency;
 - (ii) Specify a process for contacting Dispensary Agents on a 24-hour, 7-day-a-week basis through a telephone answering service or a similar service provider; and
 - (iii) Include protocols for the maintenance of life safety equipment (fire extinguishers and AEDs, for example) and the training of staff on the proper use of the same;
- B. A detailed continuity of operations (COOP) plan for the emergency administration of medication in response to inclement weather, man-made emergencies, supply chain disruptions, or discipline (including permit suspension under these regulations) which

result in the RMD being unable to provide medical marijuana and MIPs to patients with a documented medical need. This continuity of operations plan will:

- (i) Include provisions for the notification of patients in the event that inclement weather, man-made emergencies, supply chain disruptions, or discipline under these regulations might result in a temporary disruption to medication supply; and
- (ii) Include formal contractual arrangements to fulfill patient orders for medical marijuana and MIPs in the face of service disruption; these plans will specify order fulfillment and delivery arrangements with at least two (2) RMDs that are not otherwise affiliated with the applicant for a Needham RMD Permit.

Such a plan will be subject to review and approval by the Board of Health or its designated agents prior to the RMD beginning operations, and at least annually thereafter.

Comment [TM1]: Remove entirely?

24.5.5 – Safety and Security Plan Review

In accordance with the criteria specified in 105 CMR 725.110—the Security Requirements for Commercial and Recreational Marijuana Establishments—an applicant for a CRME Permit shall develop a comprehensive security plan. Such a plan will be subject to review and approval by the Director, the Chief of Police, and the Fire Chief prior to the CRME beginning operations, and at least semi-annually thereafter.

Comment [TM2]: Find or create new citation

SECTION 24.6 MARIJUANA SALES BY COMMERCIAL AND RECREATIONAL MARIJUANA ESTABLISHMENT

24.6.1 – No person or organization shall sell marijuana or marijuana-infused products from any location other than at a RMD that possesses a valid CRME Permit. A violation of this provision constitutes a MAJOR violation.

24.6.2 – A sign shall be conspicuously posted on the exterior of the establishment at each entrance to the CRME, indicating that the entry to persons under the age of 21 is prohibited. The sign shall remain unobstructed, secured to the building at a height of no less than four (4) feet or greater than seven (7) feet from the ground, and maintained in good condition. A violation of this provision shall be considered a MAJOR violation.

24.6.3 – Dispensary Agents or organizations shall verify the Registration Card or Personal Caregiver Registration Card of the Card Holder in accordance with the procedures outlined in 105 CMR 725.000 and any other directives, memorandums or notifications from DPH. In addition, the Registration Card shall be verified for each and every Card Holder or Personal Caregiver, on each and every occasion that he/she enters the RMD, without exception. The failure to verify, regardless of the prior history of the Card Holder at the RMD, constitutes a MAJOR violation of this regulation.

Comment [TM3]: Remove entirely

24.6.4 – All retail sales of marijuana and marijuana-infused products must be face-to-face between the CRME Agent and the buyer who is age 21 or older, and shall occur on the premises of the CRME, unless the buyer who is age 21 or older is the proper recipient of home delivery in accordance with all applicable state and local regulations. A violation of this provision constitutes a MAJOR violation of these regulations.

24.6.5 – No person shall:

- A. Distribute, or cause to be distributed, any free samples of marijuana or marijuana-infused products; or
- B. Accept or redeem, offer to accept or redeem, or cause or hire any person to accept or redeem, or offer to accept or redeem, through any coupon or other method, any marijuana or marijuana-infused product for less than the listed or non-discounted price; or
- C. Sell marijuana or a marijuana-infused product through any discounts (e.g., “buy-two-get-one-free”) or otherwise provide any marijuana or marijuana-infused product for less than the listed or non-discounted price in exchange for the purchase of any other product.
- D. A violation of any of the provisions of 20.6.5(A) through 20.6.5(C) shall constitute a MAJOR violation of these regulations.

24.6.6 – CRMEs are prohibited from using self-service displays. A violation of this provision shall be considered a MINOR violation.

24.6.7 – CRMEs are prohibited from using vending machines. A violation of this provision shall be considered a MINOR violation.

24.6.8 – CRMEs are prohibited from using Non-Residential Roll-Your-Own machines. A violation of this provision shall be considered a MINOR violation.

24.6.9 – A CRME and its Dispensary agents are prohibited, in accordance with restrictions outlined in 105 CMR 725.105(K) and (L), from providing:

- A. Any statement, design, representation, picture, or illustration that encourages or represents the use of marijuana for any purpose other than to treat debilitating medical condition or related symptoms;
- B. Any statement, design, representation, picture, or illustration that encourages or represents the recreational use of marijuana while driving;
- C. Any statement, design, representation, picture, or illustration related to the safety or efficacy of marijuana unless supported by substantial evidence or substantial clinical data with reasonable scientific rigor as determined by the Board of Health or its agents; or
- D. Any statement, design, representation, picture, or illustration portraying anyone under 21 years of age.
- E. A violation of any of the provisions of 20.6.9(A) through 20.6.9(D) shall constitute a MINOR violation of these regulations.

20.6.10 – A CRME, in accordance with restrictions outlined in 105 CMR 725.105(K) and (L), must adhere to the following Marketing and Advertising Requirements:

- A. A CRME may develop and use a logo for labeling, signage, and other materials, but that logo may not contain medical symbols, images of marijuana and marijuana-related paraphernalia, or colloquial references to cannabis and marijuana. Likewise, a RMD may not offer for sale or as a promotional gift any items which contain symbol of or references to marijuana or MIPs, including the logo of the RMD.
- B. A RMD may only identify the building/RMD location by the registered name, and shall not display advertisements for marijuana or any brand name nor utilize graphics related to marijuana or paraphernalia on the building.

Comment [TM4]: Find new citation or remove entirely

Comment [TM5]: Remove entirely?

Comment [TM6]: Find new citation or revise/remove entirely.

Comment [TM7]: Good! Retain if possible.

- C. CRME external signage shall not be illuminated except for a period of 30 minutes before sundown until closing, and shall comply with Article 5 of the Town of Needham By-Laws which regulates signage advertising. Neon signage is prohibited at all times.
- D. No marijuana, MIPs, and other related products shall be visible or displayed in such a way as to be seen from the exterior of a CRME. Within the CRME, one sample of each marijuana strain and each MIP may be displayed in a transparent and locked case.
- E. Inside the CRME, all marijuana which is not displayed in accordance with state and local restrictions (as outlined in 105 CMR 725.105(L)(10) and in Section 20.6.10(D) above) shall be stored in a locked, access-controlled space in a limited access area during non-business hours. This access-controlled space shall be inaccessible to any persons other than dispensary agents.
- F. A RMD shall provide a catalogue or a printed list of the prices and strains of marijuana available at the RMD to registered qualifying patients and personal caregivers upon request, but shall not advertise the price of marijuana.
- G. A violation of any of the provisions of 20.6.10(A) through 20.6.10(F) shall constitute a MINOR violation.
- H. If, during the course of an inspection or compliance check at the RMD Cultivation/Production Site, mold, infestation, or other diseases affecting marijuana plants is observed, then the Board of Health or its Agents may order the segregation and/or destruction of all such plants (as well as surrounding plants) to prevent a threat to the public's health.

SECTION 20.7 HOME CULTIVATION

20.7.1 – Marijuana cultivation or processing of any kind is prohibited within the town of Needham without a RMD Permit or Home Permit issued by the Needham Board of Health.

20.7.2 – Prior to any home cultivation taking place within the town, even by a qualifying patient or caregiver under 105 CMR 725.000, the respective individual must obtain a Home Permit. Cultivation that takes place without a permit is outside the coverage of the medical marijuana program and is subject to prosecution as a crime under Massachusetts General Laws, Chapter 94C.

20.7.3 – A Home Permit shall be granted if the Board of Health determines that:

- A. The applicant does not have access to an RMD by any of:
 - (i) public or private transportation, or
 - (ii) a caregiver with transportation, or
 - (iii) a RMD that will deliver to the applicant or the applicant's caregiver's primary address.

Or that:

- B. The applicant has a verified financial hardship (as defined in 105 CMR 725.004 as enrollment in either MassHealth or Supplemental Security Income, or else that an individual's income does not exceed 300% of the federal poverty level, adjusted for family size) and does not have access to an RMD willing to provide the applicant marijuana at no or an affordable cost.

Applicants who fail to meet the above described hardship standard will not receive a Home Permit and will be informed, in a written statement, that marijuana cultivation is prohibited in Needham without a RMD Permit or Home Permit, and that any such cultivation is outside the coverage of the medical marijuana program and is subject to prosecution as a crime under Massachusetts General Laws, Chapter 94C.

20.7.4 – Subject to the provisions of Section 20.7.3, the Board of Health may issue a Home Permit authorizing cultivation activities at a specified address within the town, provided that the applicant:

- A. Submits to a pre-approval inspection by the Board of Health or its designated agents, which may include law enforcement officers and fire officials and building inspectors, to ensure that the location specified in the application meets all of the requirements of this regulation; and
- B. Meets all the requirements for home cultivation contained in 105 CMR 725.000 and any

related directives, memorandums or notifications. These include, but are not limited to, an enclosed, locked space, not viewable from a public location, in which cultivation and storage takes place in accordance with public health and safety requirements as determined by the Board; and

- C. Meets all applicable local regulations within the town including, but not limited, fire safety and building code provisions; and
- D. If not the property owner, the applicant has notified the public or private property owner of the specified address, and obtained from that owner consent to any alteration the property's fixtures or structure, including agreement concerning any increased utility costs likely to result from cultivation activities; and
- E. Grows only enough marijuana to maintain a sixty (60) day supply, which has been determined to be ten (10) ounces by DPH. The Board of Health or the Director may specifically designate the number and type of plants that may be possessed at any time by the applicant in order to meet this standard; and
- F. Submits to reasonable inspections by the Board of Health or its designated agents, which may include law enforcement officers, to ensure compliance with all of the requirements in this regulation; and
- G. Agrees that a Home Permit only allows for the cultivation and processing of marijuana without the use of any fire, heat source, or gas, except for cooking on a conventional stove originally supplied with the dwelling; and
- H. Agrees that a Home Permit does not allow any method for processing marijuana that presents a risk of explosion or other property damage by any means; and
- I. All Home Permits expire on June 30 annually, regardless of the year or day and month on which there were issued.
- J. If the Board of Health determines that the conditions to achieve the hardship standard permitting a Home Permit for marijuana cultivation no longer exist, the Board of Health may, after notice and opportunity to be heard, revoke the Home Permit and disallow cultivation of marijuana in the home setting of the affected person or persons.
- K. A violation of provision 20.7.4 (B), (C), or (D) shall constitute a MINOR violation of these regulations. A violation of provision 20.7.4 (A), (E), (F), (G), or (H) shall constitute a MAJOR violation of these regulations.
- L. If, during the course of an inspection or compliance check at the Home Permit Site, mold, infestation, or other diseases affecting marijuana plants is observed, then the

Board of Health or its Agents may order the segregation and/or destruction of all such plants (as well as surrounding plants) to prevent a threat to the public's health.

DRAFT

SECTION 24.8 VIOLATIONS

24.8.1 – The period of performance for violations of these regulations is five (5) years. MINOR violations shall be rectified within 72 hours of the violation, and shall be subject to re-inspection following that period. MAJOR violations shall be rectified within 24 hours, and shall be subject to re-inspection following that period. Prompt rectification of a violation shall not dissolve the record of the violation.

24.8.2 – In addition to any penalty that may be imposed under the non-criminal method of disposition as provided in General Laws, Chapter 40, Section 21D and Town of Needham By Laws, the Board of Health may, after a duly noticed hearing at which the CRME or Home Permit holder has had an opportunity to be heard, suspend, modify, or revoke the CRME Permit or Home Permit. The minimum suspension schedule shall be as follows:

- A. In the case of either five (5) or more MINOR violations or in the case of a MAJOR violation the CRME Permit or Home Permit shall be suspended for seven (7) consecutive business days.
- B. In the case of a second MAJOR violation or in the case of ten (10) or more MINOR violations, the CRME Permit or Home Permit shall be suspended for one (1) month.
- C. In the case of a third MAJOR violation or in the case of fifteen (15) or more MINOR violations, the CRME Permit or Home Permit shall be suspended for six (6) months.
- D. In the case of a fourth MAJOR violation or in the case of twenty (20) or more MINOR violations, the CRME Permit or Home Permit shall be suspended for twelve (12) months and may, at the Board of Health's discretion, be permanently revoked.
- E. Refusal to cooperate with the Board of Health or its designated agents is considered a separate violation of these regulations and shall result in the suspension of the RMD Permit or Home Permit for a minimum of ninety (90) consecutive business days. This shall be in addition to any other penalty imposed for other violations observed.
- F. Any CRME Permit Holder or Home Permit Holder who engages in or allows the sale, distribution or cultivation of marijuana or marijuana-infused products while his or her permit is suspended shall be subject to permanent revocation, and additional civil or criminal proceedings.

24.8.3 – The penalties mentioned in 24.8.2 represent the guidelines for action to be taken by the Board of Health for violations, and do not preclude the licensing authority from taking additional action after a duly noticed hearing at which the CRME Permit or Home Permit holder has an opportunity to be heard.

24.8.4 – If during an inspection or a compliance check, a Board of Health Agent determines a MAJOR violation of these regulations exists or has occurred, the Director may temporarily suspend the CRME Permit or Home Permit for a period not to exceed 96 hours while public notice of a scheduled Board of Health hearing is posted in accordance with the provisions of the Massachusetts Open Meeting Law (M.G.L. c. 30A, §§ 18-25).

24.8.5 – If a CRME permit is suspended, the permit holder shall cease sale and distribution of marijuana or marijuana-infused products, and close and secure the CRME premises to the satisfaction of the Director or his/her agents for the period of the suspension. Additionally, notice of the suspension must be publicly posted on the CRME, the CRME's website, and the Town of Needham's website, all to the satisfaction of the Director or his/her agents.

24.8.6 – If a CRME permit is revoked, the permit holder shall cease all sale, distribution or cultivation of marijuana or marijuana-infused products, and shall close and secure the RMD premises to the satisfaction of the Director or his/her agents, and the RMD shall submit subject to the approval of the Board or its designated agents, or the Board may order, implementation of a plan for the removal of marijuana and marijuana-infused products and related implements and equipment from the CRME retail establishment. Additionally, notice of the revocation must be publicly posted on the CRME, the CRME's website, and the Town of Needham's website, all to the satisfaction of the Director or his/her agents.

24.8.7 – In the case of a suspension or revocation of a Home permit, the Board may order that marijuana or marijuana-infused products and related implements and equipment be removed from the specified Home permit location. The method for removal and storage, and the deadline for compliance, may be specified in the Board's order or at the direction of the Director. In the case of a Home permit, the Board may authorize immediate confiscation of all the items previously mentioned prior to, or after, the hearing, provided that any removed items are not damaged prior to the conclusion of all administrative actions and appeals. Removal and storage of live marijuana plants does not obligate the Board or its agents to assure the maintenance of the plants during the period of suspension or confiscation.

24.8.8 – In the event that a CRME permit or Home permit is suspended or modified, the Permit holder may be ordered to submit a remediation plan addressing all causes for the suspension or modification and all appropriate changes to business practices and operations. That remediation plan is subject to review and approval by the Board of Health prior to reinstating the permit.

SECTION 24.9 ENFORCEMENT

24.9.1 – Enforcement of this Regulation shall be by the Board of Health and its designated agents.

24.9.2 – Whoever violates any provision of this regulation may be penalized by the non-

criminal method of disposition as provided in General Laws, Chapter 40, Section 21D and Town of Needham By Laws, or by filing a criminal complaint.

24.9.3 – Each day any violation exists shall be deemed to be a separate offense.

24.9.4 – Any resident who desires to register a complaint pursuant to this Regulation may do so by contacting the Board of Health, the Public Health Department, or the Needham Police Department.

SECTION 24.10 SEVERABILITY

If any provision of these regulations is declared invalid or unenforceable, the other provisions shall not be affected thereby but shall continue in full force and effect.

SECTION 24.11 EFFECTIVE DATE

This regulation shall take effect upon December 20, 2016. Public hearings and open meetings regarding this regulation were conducted on November 10, 2016 and December 2, 2016. This regulation was approved by a unanimous vote of the Board of Health on December 2, 2016.